K102709

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PEAK surgical

510(k) Summary:
PEAK PlasmaBlade® PLUS

DEC 17 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

1. Submitter Name and Address:

PEAK Surgical, Inc.
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Contact: Lois Nakayama
Sr. Manager, Regulatory Affairs

Date prepared: December 3, 2010

2. Device Name:

Trade Name: PEAK PlasmaBlade® PLUS

Common Name: Electrosurgical Device and Accessories

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

Regulation Number: 21 CFR § 878.4400

Product Code: GEI

Regulatory Class: Class II

3. Predicate Devices:

PEAK PlasmaBlade® 3.0S (K093695)
PEAK PlasmaBlade® TnA (K083415)
ConMed Ball Electrode (K780976)

4. Device Description:

The PEAK PlasmaBlade® PLUS consists of a single insulated bendable blade, telescoping shaft that can be configured in both standard and extended length and a handle with integrated controls and cable. The finger grip incorporates a suction lumen for the evacuation of smoke and fluids. A ball electrode attaches to the finger grip to allow a broader application of energy.

The PlasmaBlade PLUS is an addition to the PEAK PlasmaBlade Family of Tissue Dissection devices which include the PlasmaBlade 4.0, PlasmaBlade Needle, PlasmaBlade EXT and PlasmaBlade 3.0S.

5. Intended Use:

The PEAK PlasmaBlade® PLUS is indicated for cutting and coagulation of soft tissue during General, Plastic and reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological surgical procedures.

6. Technological Characteristics

The PEAK PlasmaBlade® PLUS is similar to the predicate devices in output energy, delivery system (PlasmaBlade 3.0S) and blade specifications (ConMed Ball Electrode). The PlasmaBlade 3.0S and PlasmaBlade PLUS are both electrosurgical instruments used to cut and coagulate soft tissue, utilizing RF powered distal ends.

7. Non-clinical Performance Data:

Laboratory and performance tests were executed to ensure that the device functioned as intended and met design specifications. Data demonstrated that the PlasmaBlade PLUS complies with the following standards:

- IEC 60601-1; Medical Electrical Equipment – Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- IEC 60601-1-2; Medical Electrical Equipment – Part 1-2: General Requirements for Safety: Electromagnetic Compatibility, 2001, Amendment 1: 2004.
- IEC 60601-2-2; Medical Electrical Equipment – Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment (Fourth Edition, 2006)

- ISO 11135-1; Sterilization of Healthcare Products – Ethylene Oxide – Part1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices (First Edition, 2007)

- ISO 10993-1; Biological evaluation of medical devices – Part 1: Guidance on selection of tests (Third Edition, 2003)

- ISO 10993-7; Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals (First Edition, 1995)

Histological studies comparing thermal effects of the device to the predicate devices demonstrated that the PlasmaBlade PLUS is substantially equivalent to the predicate devices and meets safety and effectiveness criteria.

8. Sterilization

The PEAK PlasmaBlade® PLUS is provided sterile. The device is not intended for reuse or resterilization.

9. Conclusion:

By virtue of design, materials, function and intended use, the PEAK PlasmaBlade® PLUS is substantially equivalent to the predicate devices. In establishing substantial equivalence to the predicate device, PEAK Surgical evaluated the indications for use, materials incorporated, product specification and energy requirements of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

PEAK Surgical Inc.
% Ms. Lois Nakayama
Senior Manager, Regulatory Affairs
2464 Embarcadero Way
Palo Alto, California 94303

DEC 17 2010

Re: K102709
Trade/Device Name: PEAK PlasmaBlade® PLUS
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 16, 2010
Received: November 17, 2010

Dear Ms. Nakayama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: PEAK PlasmaBlade® PLUS

Indications for Use:

The PEAK PlasmaBlade® PLUS Tissue Dissection Device is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological surgical procedures.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102709

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)